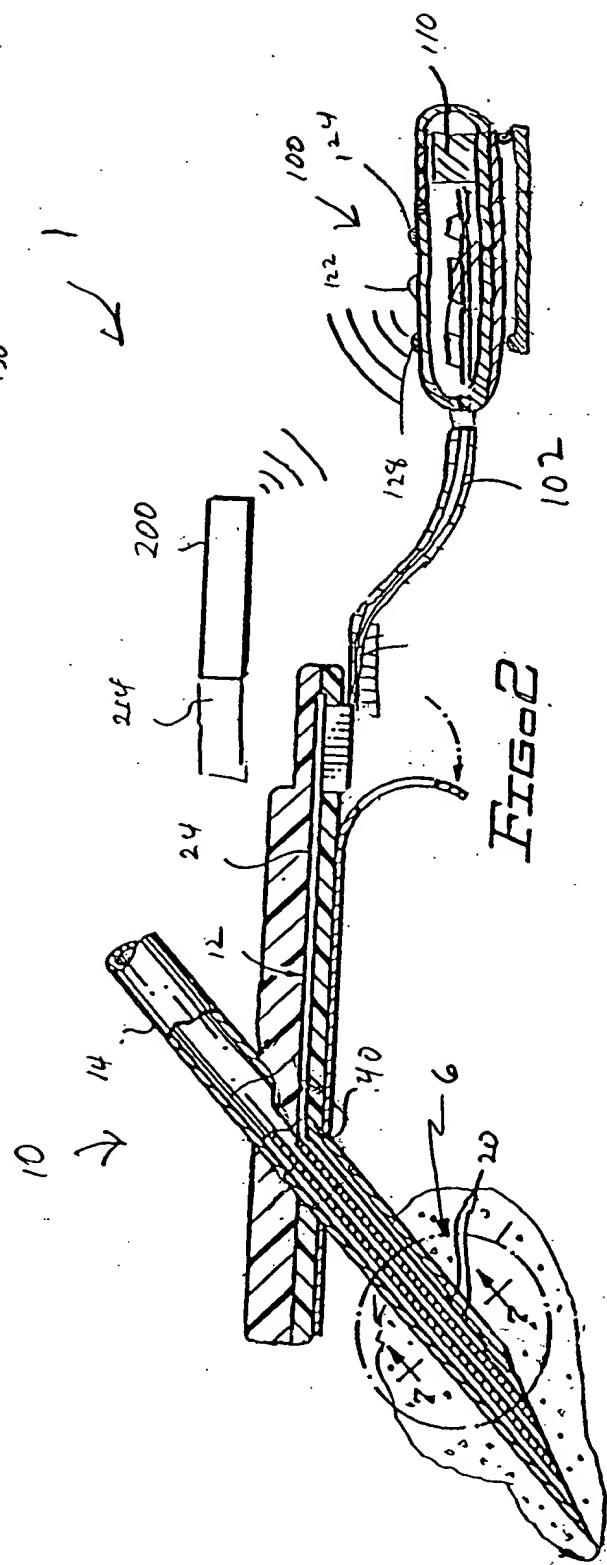
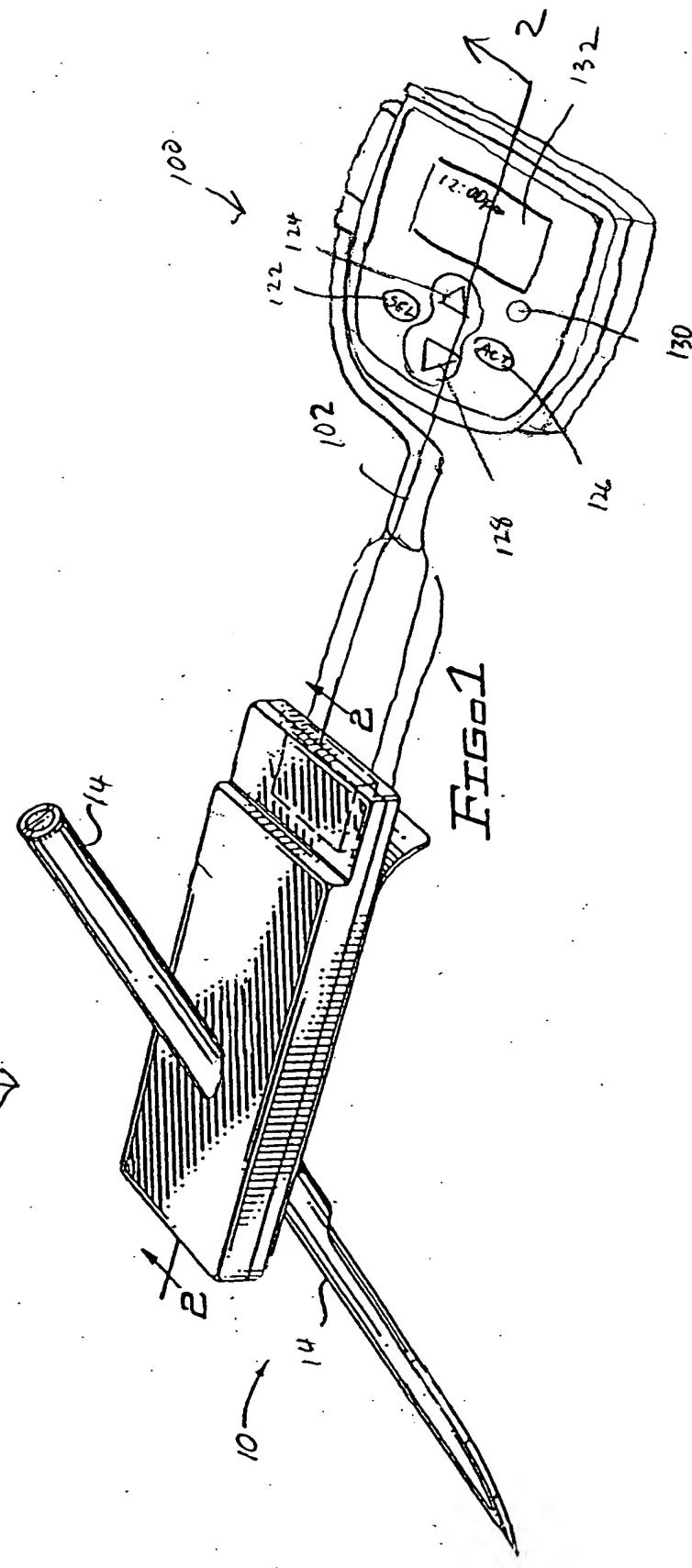


002200-08577560



14

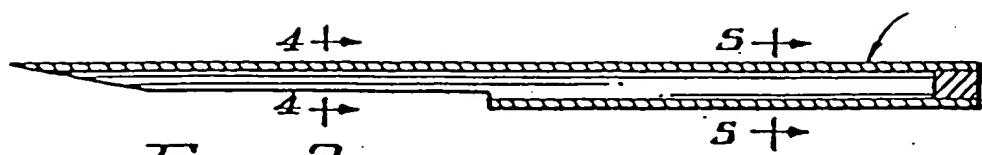


FIG. 3

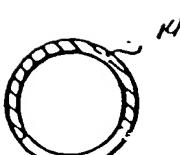


FIG. 4

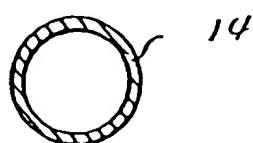


FIG. 5

14

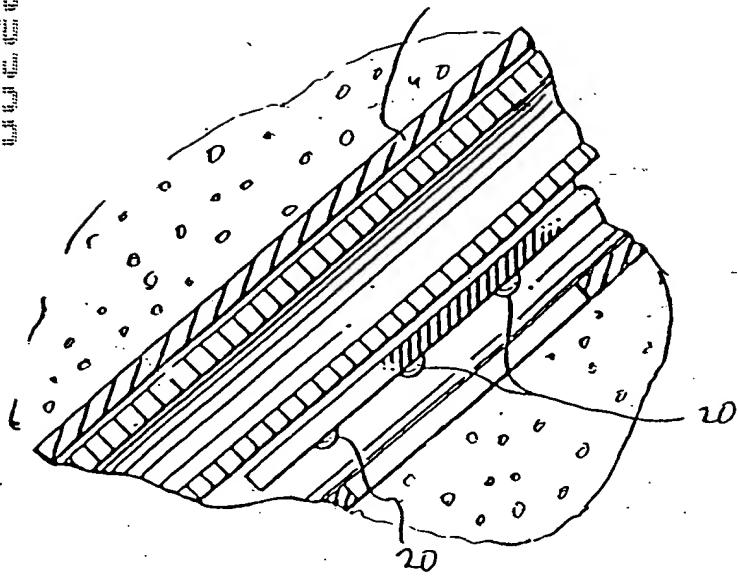


FIG. 6

14

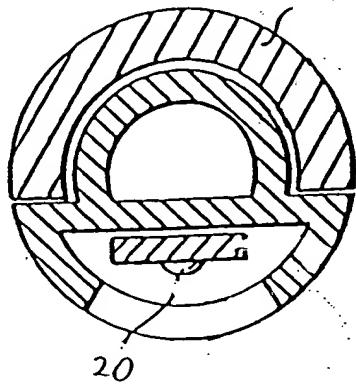


FIG. 7

Digitized Data in Fig. 8

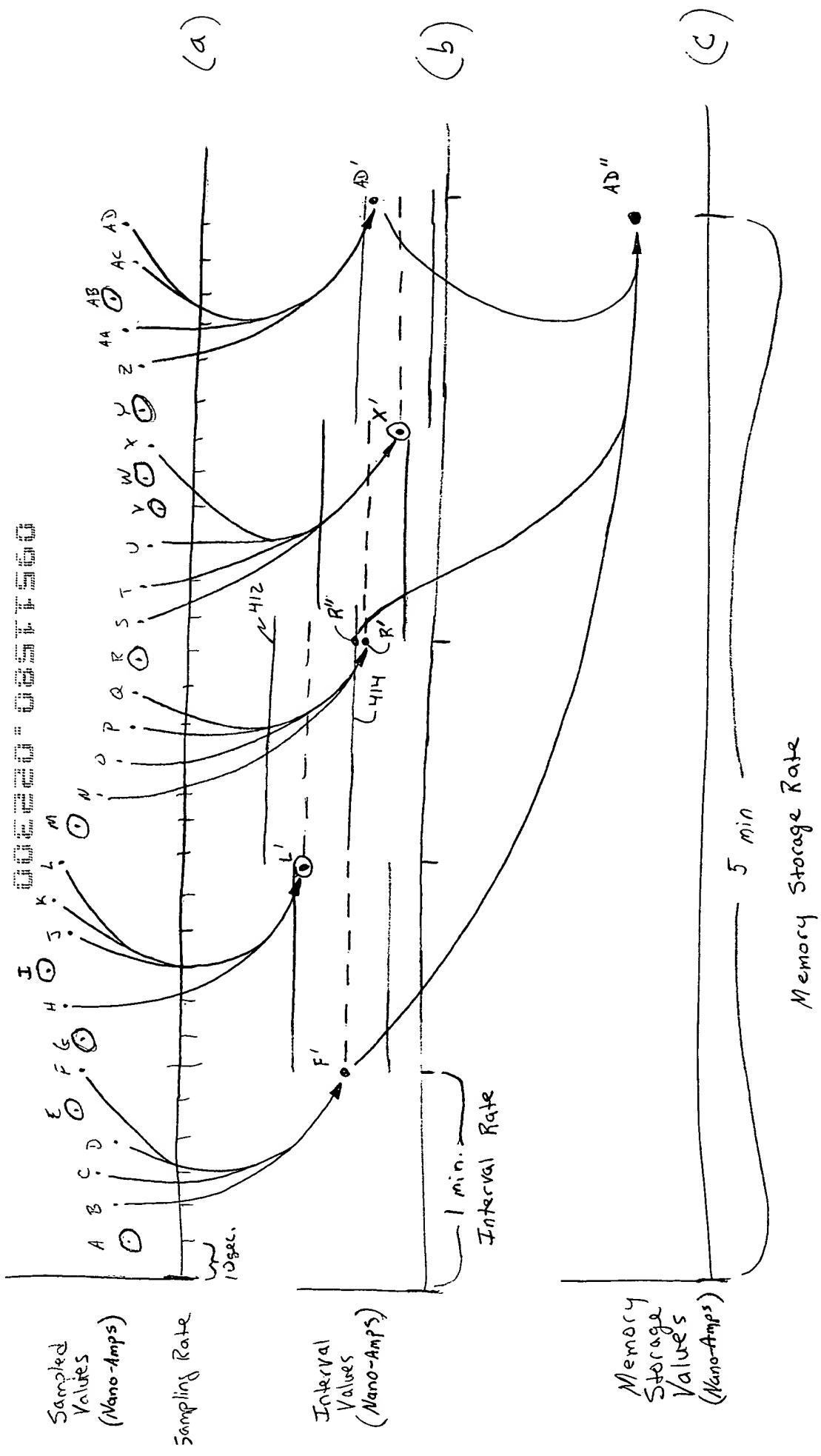


Fig. 8

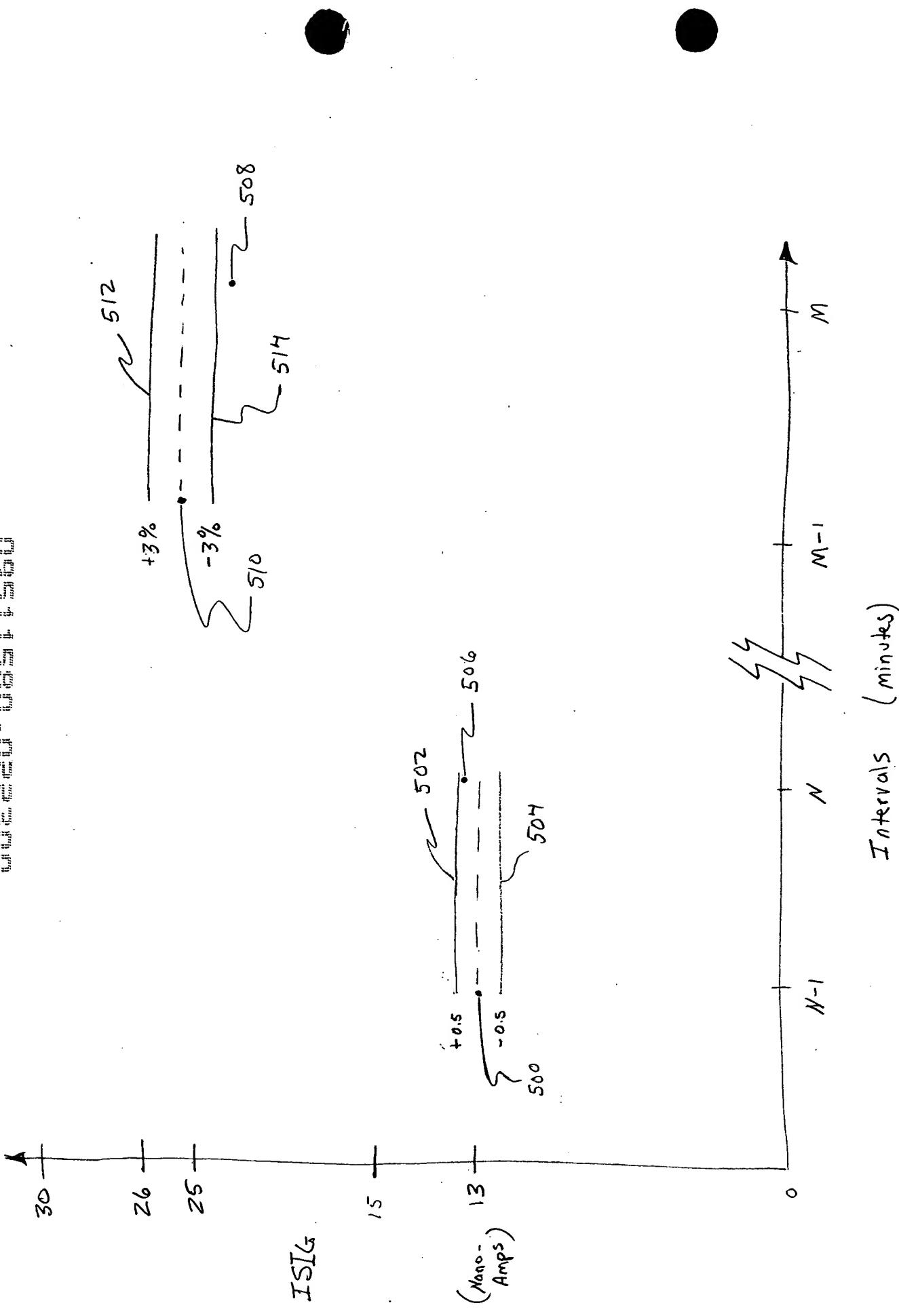


Fig. 9

Microsoft Excel - P000-0010@11-59-11@7-13-1998.FDA

	Percent ID	Sample	Date	Time	ISIG Value	VCTR	Meter Value	Slope	Offset	Valid ISIG	Sensor Value	Power Up	Power Down	Sensor Initialization	Link Event	Sensor Disconnected
1	000-0000	0	7/10/98	10:53	0	-2.042										
2	000-0000	1	7/10/98	10:58	0	-2.026										SeDi
3	000-0000	2	7/10/98	11:03	0	-1.732										
4	000-0000	3	7/10/98	11:09	99.1	-0.936										
5	000-0000	4	7/10/98	11:14	19.7	-0.955										
6	000-0000	5	7/10/98	11:19	26.1	-0.998										
7	000-0000	6	7/10/98	11:24	25.7	-0.626										
8	000-0000	7	7/10/98	11:29	26	-0.643										
9	000-0000	8	7/10/98	11:34	24.9	-0.648										
10	000-0000	9	7/10/98	11:39	23.9	-0.649										
11	000-0000	10	7/10/98	11:44	23.8	-0.651										
12	000-0000	11	7/10/98	11:49	24.3	-0.650										
13	000-0000	12	7/10/98	11:54	23.9	-0.655										
14	000-0000	13	7/10/98	11:59	23	-0.652										
15	000-0000	14	7/10/98	12:04	23.3	-0.652										
16	000-0000	15	7/10/98	12:09	22.2	-0.645									ESI	
17	000-0000	16	7/10/98	12:14	22.1	-0.644	95	5.0	3	22.1	95					
18	000-0000	17	7/10/98	12:19	20.1	-0.634				20.1	86					
19	000-0000	18	7/10/98	12:24	19.9	-0.637				19.9	85					
20	000-0000	19	7/10/98	12:29	20.6	-0.645				20.6	88					
21	000-0000	20	7/10/98	12:34	20.8	-0.662				20.8	89					
22	000-0000	21	7/10/98	12:39	19.1	-0.645				19.1	81					
23	000-0000	22	7/10/98	12:44	18.2	-0.636				18.2	76					
24	000-0000	23	7/10/98	12:49	17.4	-0.633				17.4	72					
25	000-0000	24	7/10/98	12:54	16.4	-0.625				16.4	67					
26	000-0000	25	7/10/98	12:59	15.7	-0.619				15.7	64					
27	000-0000	26	7/10/98	13:04	15	-0.612				15	60					
28	000-0000	27	7/10/98	13:09	13.8	-0.602				13.8	54					
29	000-0000	28	7/10/98	13:14	13.3	-0.597				13.3	52					
30	000-0000	29	7/10/98	13:19	14.4	-0.62				14.4	57					
31	000-0000	30	7/10/98	13:24	16	-0.635				16	65					
		31	7/10/98	13:29	15.1	-0.57										

Fig. 10

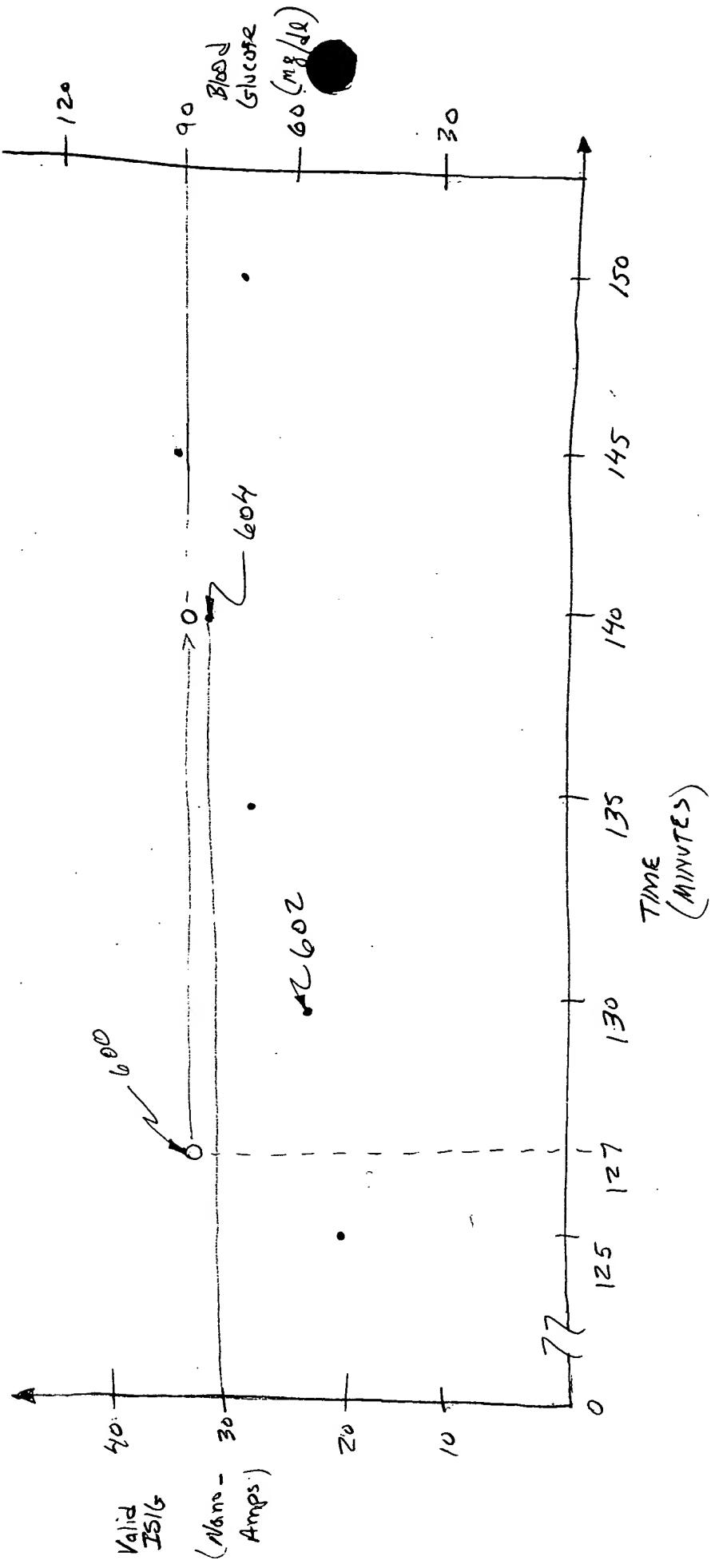


Fig. 11

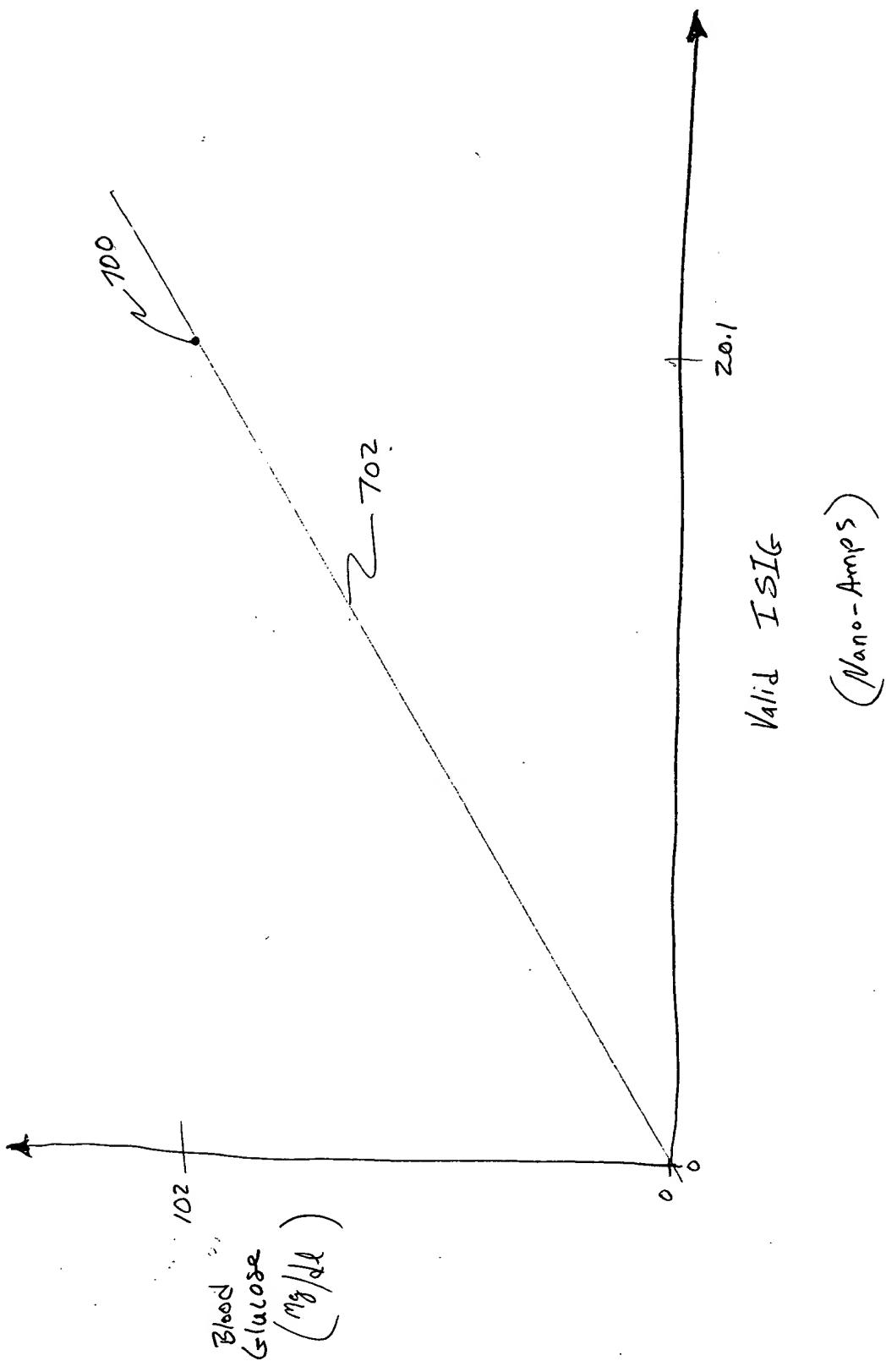


Fig. 12

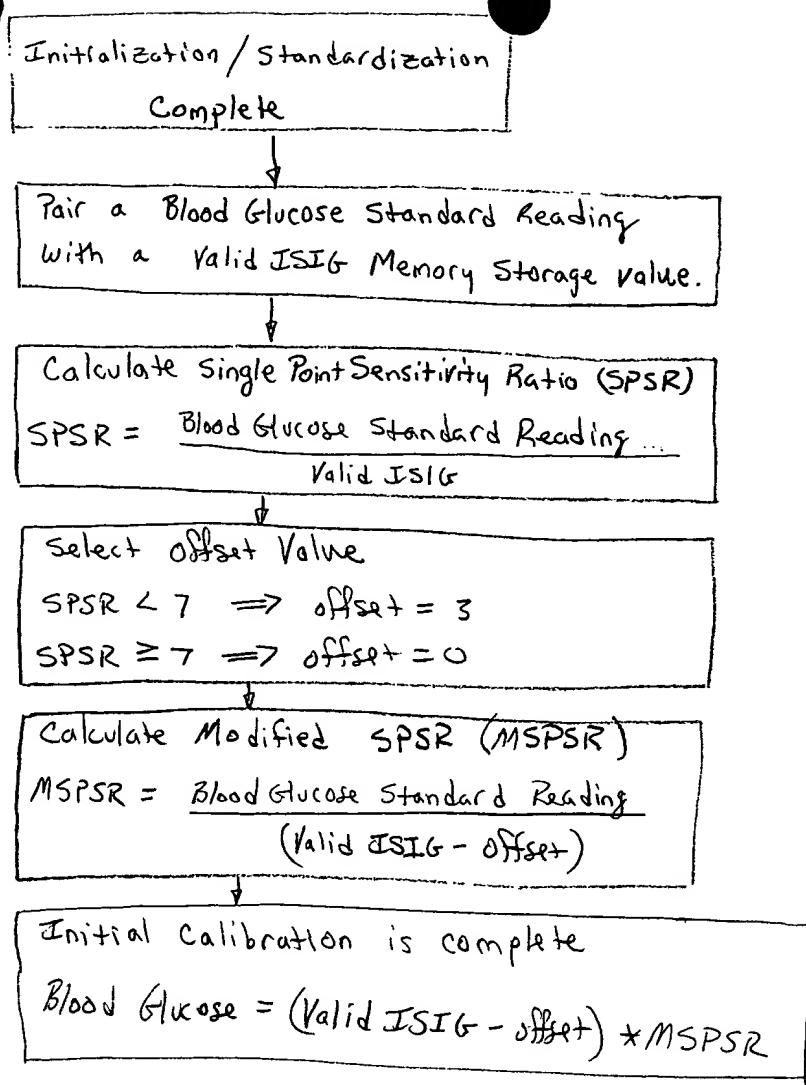


Fig. 13

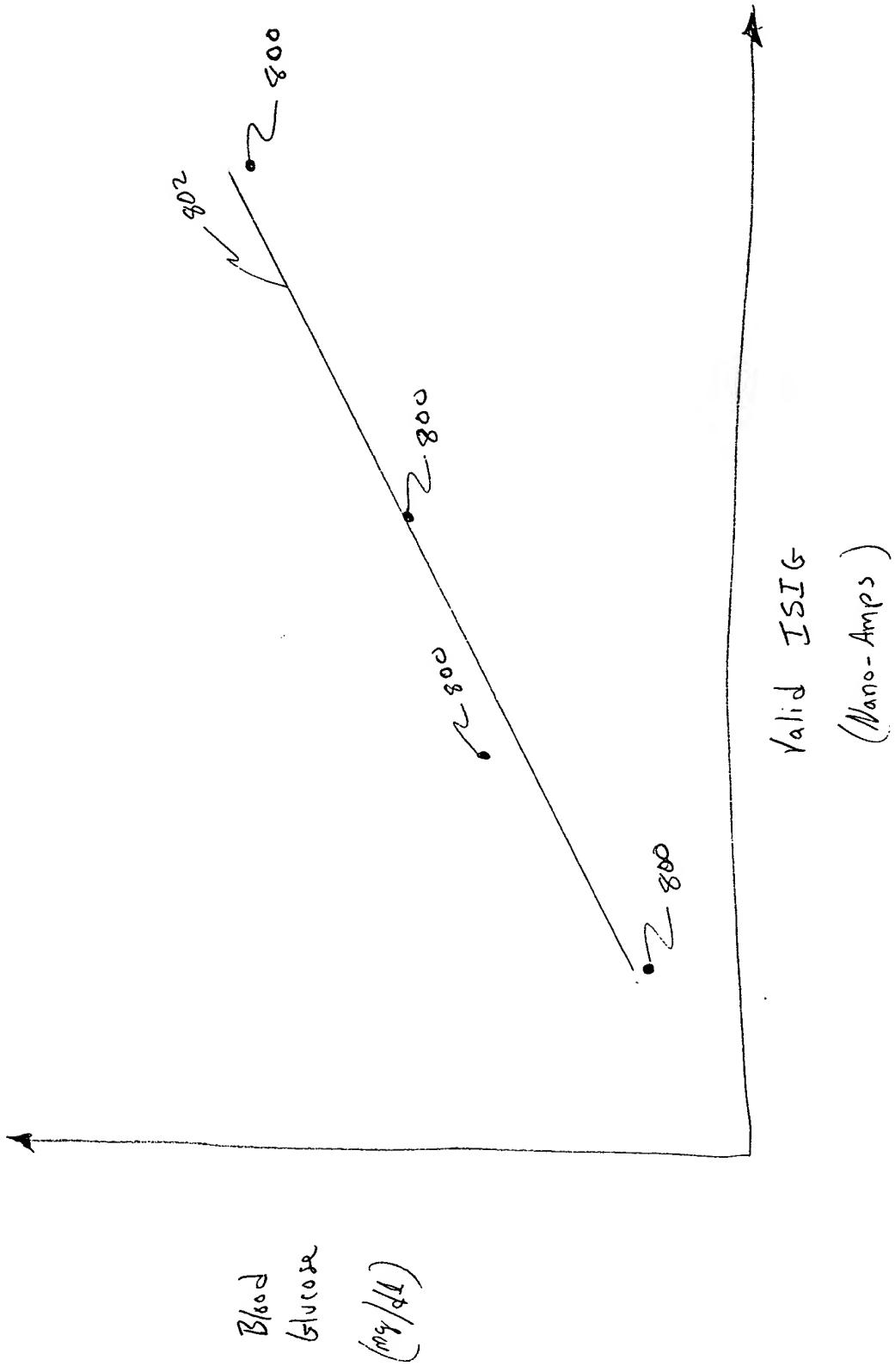


Fig. 14

2 or more paired calibration data points are available.



Calculate Linear Regression Sensitivity Ratio (LRSR)

$$LRSR = \frac{\sum_{i=1}^N [X_i Y_i]}{\sum_{i=1}^N [X_i^2]}$$

$i$  = the  $i$ th pair

where  $X$  = Valid ISIIG

$Y$  = Blood Glucose Standard Reading

$N$  = Number of paired calibration data points

Select Offset Value

$$LRSR < 7 \Rightarrow \text{offset} = 3$$

$$LRSR \geq 7 \Rightarrow \text{offset} = 0$$

Calculate Modified LRSR (MLRSR)

$$MLRSR = \frac{\sum_{i=1}^N [(X_i - \text{offset}) Y_i]}{\sum_{i=1}^N [(X_i - \text{offset})^2]}$$

Calibration is complete

$$\text{Blood Glucose} = (\text{Valid ISIIG} - \text{offset})(MLRSR)$$

Fig. 15